IN THE UNITED STATES DISTRICT COURT
FOR THE MIDDLE DISTRICT OF PENNSYLVANIA

PACIFIC EDGE DIAGNOSTICS, USA, LTD.,	:	**CIVIL ACTION NO. 1:25-CV-291**
	:	
	:	**(Judge Neary)**
Plaintiff	:	
	:	
v.	:	
	:	
ROBERT F. KENNEDY, in his official capacity as Secretary of Health and Human Services, and NOVITAS SOLUTIONS, INC.,	:	
	:	
Defendants	:	

MEMORANDUM

Plaintiff Pacific Edge Diagnostics, USA, Ltd. initiated this action to challenge a Medicare coverage determination made by defendant Novitas Solutions, Inc. Novitas, pursuant to authority granted to it by the Secretary of Health and Human Services, determined a test manufactured by Pacific Edge and used by physicians to rule out bladder cancer would no longer be covered by Medicare. Pacific Edge challenges this determination as arbitrary and capricious under the Administrative Procedure Act, 5 U.S.C. § 706(2)(A). The Secretary and Novitas (collectively "Defendants") have asked this court to dismiss Pacific Edge's challenge for a lack of jurisdiction. Because Pacific Edge will have an administrative remedy available to it if a claim is denied, the statutory scheme Defendants' motion to dismiss will be granted.

I. Factual Background & Procedural History

A. The Medicare Act

Medicare is a public health program providing health benefits to all persons aged sixty-five and older who are eligible for Social Security benefits or eligible for retirement benefits under the railroad retirement system. 42 U.S.C. §§ 1395 *et seq*. Among Medicare's provisions is Medicare Part B, which covers certain physicians' services, outpatient hospital care, and other medical items and services. California Clinical Lab'y Ass'n v. Sec'y of Health & Hum. Servs., 104 F. Supp. 3d 66, 70 (D.D.C. 2015).

The Secretary administers Medicare through the Centers for Medicare and Medicaid services ("CMS"). Additionally, the Secretary can enter into contracts with private entities, known as Medicare Administrative Contractors ("MAC's"), who are then empowered to make certain coverage determinations. 42 U.S.C. § 1395kk-1(a)(1), (4); 42 U.S.C. 1395u(a). Specifically, a MAC can issue a local coverage determination ("LCD") establishing "whether or not a particular item or service is covered" within the geographic region assigned to the MAC. 42 U.S.C. § 1395ff(f)(2)(B). In this way, an LCD serves as a first-step screen of what is and is not covered by Medicare.

A MAC's discretion in issuing an LCD is not limitless. An LCD may only cover expenses that are "reasonable and necessary" for healthcare. 42 U.S.C. § 1395y(a)(1)(A). Also, an LCD must first go through a notice and comment period seeking feedback from the public and stakeholders. Medicare Program Integrity Manual ("PIM"), § 13.2.4. LCD's for clinical diagnostic laboratory services must be

made with the same process for making other local coverage determinations. 42 U.S.C. § 1395m-1(g)(1)(A).

Individual beneficiaries, healthcare providers, and suppliers of covered items may challenge a coverage determination through an administrative process after a MAC denies a claim. See 42 U.S.C. §§ 1395ff(b)–(d); 42 C.F.R. § 405.900 *et seq*. First, a dissatisfied person or entity can seek a redetermination. 42 U.S.C. § 1395ff(a)(3); 42 C.F.R. § 405.940. The next step is to seek review by a qualified independent contractor,[1] 42 U.S.C. § 1395ff(c); 42 C.F.R. § 405.960, who is not bound by the LCD, 42 U.S.C. § 1395ff(c)(3)(B)(ii)(II). After that, a challenger may seek review before an administrative law judge ("ALJ"). 42 U.S.C. §§ 1395ff(d)(1); 42 C.F.R. § 405.1000. The final administrative stop is an appeal to the Medicare Appeals Council, a division of the Departmental Appeals Board of the Department of Health and Human Services ("DAB"). 42 U.S.C. §§ 1395ff(d)(2); 42 C.F.R. § 405.1100.

Like the qualified independent contractors, neither the ALJs nor the DAB "are not bound by LCDs" when hearing appeals from initial coverage determinations. 42 C.F.R. § 405.1062(a). This is to say, notwithstanding the LCD, an ALJ or the DAB can still find a test to be reasonable and necessary—and covered by Medicare. At the same time, neither ALJs nor the DAB can invalidate an LCD

[1] A qualified independent contractor is an entity or organization that is independent of any MAC that additionally possesses "sufficient medical, legal, and other expertise" to evaluate whether a test or service is reasonable and necessary under Medicare. 42 U.S.C. § 1395ff(c)(2), (c)(2)(3)(A).

wholesale on behalf of a supplier.[2] Id. § 405.1062(c). Once an adverse DAB decision becomes final, then and only then, can an appellant seek judicial relief. See 42 U.S.C. § 405(g), (h);[3] 42 C.F.R. § 405.1136(a)(1).

B. The Dispute

Pacific Edge is a biotechnology supplier that makes the Cxbladder line of tests to help rule out or monitor urothelial bladder cancer in patients with hematuria. (Doc. 1 ¶¶ 1, 6). Since 2020, Novitas[4] has regularly approved claims for Cxbladder tests. (Id. ¶ 48). In 2022, Novitas began the process for updating its LCD. (Id. ¶ 49). The first draft, published and open to comment on June 9, 2022, stated that only tests approved by certain non-profits, National Comprehensive Cancer Network ("NCCN") Biomarkers Compendium, Memorial Sloan Kettering Cancer Center Oncology Knowledge Base ("OncoKB"), or Clinical Genome Resource ("ClinGen"), would be covered. (Id. ¶ 50). Cxbladder was not approved by any of these organizations. (Id. ¶ 55).

After a series of meetings, Novitas was preparing to finalize a new LCD, L39365, in mid-2023. (Id. ¶¶ 55, 57). This LCD stood by the requirement that tests be

[2] Individuals, however, can utilize a special avenue to challenge an entire LCD. See 42 U.S.C. § 1395ff(f)(2)(A), (f)(5).

[3] Section 405, by its own terms, applies to the Social Security Administration. Subsection (h) incorporated by reference to apply to Medicare by 42 U.S.C. § 1395ii and subsection (g) is incorporated by reference by 42 U.S.C. 1395ff(b)(1)(A).

[4] Novitas is the MAC for Arkansas, Colorado, Delaware, Louisiana, Maryland, Mississippi, New Jersey, New Mexico, Oklahoma, Pennsylvania, and the District of Columbia. (Doc. 31 ¶ 8).

approved by the independent non-profits. (Id. ¶ 55). Further, L39365 included an evidence review laying out why Cxbladder tests would no longer be covered. (Id.).

Rather than finalizing L39365, Novitas reissued it as a draft—with the same provisions—and held more meetings with stakeholders, including Pacific Edge. (Id. ¶¶ 59-60). On January 3, 2025, Novitas repromulgated L39365 with an effective date of February 23, 2025. (Id. ¶ 72). This latest LCD dropped the explicit requirement tests be approved by the independent non-profits, however, it explicitly would not cover Cxbladder tests. (Id.). On January 27, 2025, Novitas announced the effective date for the final LCD is April 24, 2025. (Id. ¶ 74). While typically LCD's are only binding in the geographic region covered by a MAC, 42 U.S.C. § 1395ff(f)(2)(B), Pacific Edge asserts that because its labs are within Novitas' assigned geographic area, L39365 would have the effect of being a national non-coverage of the Cxbladder tests, (Doc. 38 at 18 n.2).

C. Procedural History

On February 18, 2025, Pacific Edge commenced this action by filing suit against Defendants, alleging violations of the Administrative Procedure Act, 5 U.S.C. § 706(2)(A) ("APA") based on Novitas's non-coverage decision of Cxbladder. (See generally Doc. 1). The next day, Pacific Edge filed a motion for a preliminary injunction (Doc. 3).[5] This court held a telephone conference on February 26, 2025, and set a briefing schedule for the preliminary injunction, Defendants' anticipated

[5] That motion also requested the court enter summary judgment along with the preliminary injunction.

motion to dismiss, and motion for summary judgment.[6] (Docs. 14, 15). On March 19, 2025, Defendants filed a motion to dismiss this case, raising a factual challenge to the court's jurisdiction over this matter. (Doc. 29). The court heard oral argument on the motion for a preliminary injunction, as well as Defendants' motion to dismiss, on April 16, 2025.

II. Legal Standard

Federal Rule of Civil Procedure 12(b)(1) provides that a court may dismiss a claim for lack of subject matter jurisdiction. See FED. R. CIV. P. 12(b)(1). Such jurisdictional challenges take one of two forms: (1) parties may levy a "factual" attack, arguing that one or more of the pleading's factual allegations are untrue, removing the action from the court's jurisdictional ken; or (2) they may assert a "facial" challenge, which assumes the veracity of the complaint's allegations but nonetheless argues that a claim is not within the court's jurisdiction. Lincoln Benefit Life Co. v. AEI Life, LLC, 800 F.3d 99, 105 (3d Cir. 2015). "A factual challenge allows 'a court [to] weigh and consider evidence outside the pleadings.'" Davis v. Wells Fargo, 824 F.3d 333, 345 (3d Cir. 2016) (citing Constitution Party of Pa. v. Aichele, 757 F.3d 347, 358 (3d Cir. 2014)). "'[T]he plaintiff will have the burden of proof that jurisdiction does in fact exist,' and the court 'is free to weigh the evidence and satisfy itself as to the existence of its power to hear the case.'" Id.

[6] On March 12, 2025, the court amended the briefing schedule at the request of Defendants and ordered that neither they nor any amicus need address Pacific Edge's alternative motion for summary judgment. (Doc. 20).

(quoting Mortenson v. First Fed. Sav. & Loan Ass'n, 549 F.2d 884, 891 (3d Cir. 1977)).

"Federal courts are courts of limited jurisdiction. They possess only that power authorized by Constitution and statute. . . . It is to be presumed that a cause lies outside this limited jurisdiction and the burden of establishing the contrary rests upon the party asserting jurisdiction." Kokkonen v. Guardian Life Ins. Co. of Am., 511 U.S. 375, 377 (1994) (internal citations omitted).

III. Discussion

Pacific Edge argues in favor of subject matter jurisdiction by framing the dispute under the APA and arising under this court's general jurisdiction over federal laws pursuant to 28 U.S.C. § 1331. Defendants counter that Pacific Edge must channel its claims through Medicare's administrative process first, before it can bring a claim in federal court. The court agrees that it lacks subject matter jurisdiction to hear this claim based on the facts as they are now.

Unquestionably, the Medicare Act is a federal statute, and APA claims are typically judiciable by federal courts. Yet, several exceptions to this general rule exist. Congress can provide for other, exclusive methods for judicial review as part of its power to set the jurisdiction of federal courts. See Shalala v. Illinois Council on Long Term Care, Inc., 529 U.S. 1, 10 (2000). The question presently before the court is whether the exclusive track set forth in the Medicare Act applies to this case.

Section 405(h) places sharp restrictions on a party's ability to sue the government for claims involving Medicare. See Illinois Council, 529 U.S. at 10. That

section "channels most, if not all, Medicare claims through [Medicare's] special review system." Id. at 8. As our court of appeals has noted, the channeling provision "operates as [a] near-absolute bar to federal-question jurisdiction for claims arising under the Medicare Act that have not been challenged administratively." Temple Univ. Hosp. v. Sec'y United States Dep't Health and Human Servs., 2 F.4th 121, 128 (3d Cir. 2021). It is undisputed Pacific Edge's claim arises under the Medicare Act, (Doc. 38 at 9), and that Pacific Edge has not yet pursued any administrative review of its claims.[7]

However, there is an exception to the exception that allows a party to bypass § 405(h)'s jurisdictional limit. To find § 405(h) inapplicable, a party must show "application of § 405(h) would not simply channel review through the agency, but would mean no review at all." Illinois Council, 529 U.S. at 19.

Pacific Edge fails to make this showing. It is undisputed that once L39365 goes into effect, Pacific Edge, as a supplier, would have standing to challenge an initial determination that non-covers a Cxbladder test. 42 C.F.R. § 405.940; 42 U.S.C. § 1395ff(a)(3). Such a challenge begins the administrative process which culminates in a final agency decision by the DAB. 42 U.S.C. §§ 1395ff(b)(1)(A), (d)(2); 42 C.F.R. § 405.1100. The decision of the DAB is subject to judicial review. 42 U.S.C. §§ 405(g), 1395ff(b)(1)(A); 42 C.F.R. 405.1136(a). Further, Pacific Edge may assist an aggrieved

[7] Indeed, Pacific Edge could not have availed itself of any administrative process because the first step is to first receive an adverse "initial determination" which will not occur until L39365 takes effect on April 24th, 2025. 42 U.S.C. § 1395ff(b)(1)(A).

party in bringing a challenge to a coverage determination before an ALJ and the DAB, and decisions of the DAB are again subject to review in federal courts. Medicare Program: Review of National Coverage Determinations and Local Coverage Determinations, 68 FED. REG. 63692, 63695 (Nov. 7, 2003); 42 U.S.C. § 1395ff(f)(2), (f)(2)(A)(iv). Thus, Pacific Edge has both a direct and an indirect avenue to court to challenge the non-coverage of its tests and so it *must* take that road, no matter how long, winding, or uncertain it may be. See Illinois Council, 529 U.S. at 12-13. (noting that the channeling requirement "comes at a price, namely, occasional individual, delay-related hardship."). Nothing in the record or legal precedent permits this Court to reach a different conclusion.

Pacific Edge, perhaps understandably, wishes to avoid taking the above avenues because the administrative process would not be able to invalidate the LCD, in addition to the delays in waiting for the administrative process to play out. (See Doc. 38 at 9-11). While an individual with aligned interests could carry its claims through the administrative process, Pacific Edge dubs this possibility "rank speculation." (Id. 11). Yet, even ignoring this route, Pacific Edge could still challenge, on an individual basis, the initial determinations denying Cxbladder tests. 42 C.F.R. § 405.940; 42 U.S.C. § 1395ff(a)(3). Pacific Edge argues that is futile because "[it] cannot challenge the validity of the LCD—meaning, the reasonableness of the LCD—in the claim appeal. Pacific Edge cannot ask the ALJ or the Council to set aside or invalidate the LCD." (Doc. 38 at 15).

Unfortunately for Pacific Edge, the Supreme Court has made clear "[t]he fact that the agency might not provide a hearing for that *particular contention*, or may

lack the power to provide one, . . . is beside the point because it is the 'action' arising under the Medicare Act that must be channeled through the agency." Illinois Council, 529 U.S. at 23 (emphasis in original) (citations omitted). "[A]ll inextricably intertwined claims must first be raised in an administrative process. In that process, the agency, with the benefit of its experience and expertise, can resolve whatever issues it can, limiting the number of issues before judicial review. . . ." Nichole Med. Equip. & Supply, Inc. v. TriCenturion, Inc., 694 F.3d 340, 350 (3d Cir. 2012) (quoting Kaiser v. Blue Cross of Cal., 347 F.3d 1107, 1116 n.4 (9th Cir. 2003)).

Pacific Edge protests, saying that since "the validity of the LCD is irrelevant to the claim denial that is the subject of the ALJ hearing, Pacific Edge cannot obtain the administrative record for the LCD through discovery in the claim appeal process." (Doc. 38 at 15). It also states that "judicial review [would be] limited to the agency's application of the LCD to the claim." (Id. at 16). Not so. Once Pacific Edge's claim has been properly channeled, "a court reviewing [the final agency action] has adequate authority to resolve *any* statutory or constitutional contention that the agency does not, or cannot, decide, including, where necessary, the authority to develop an evidentiary record." Illinois Council, 529 U.S. at 23-24 (emphasis added). The ultimate question for the court would be whether Cxbladder tests are "reasonable and necessary" for medical treatment. 42 U.S.C. § 1395y(a)(1)(A). If L39365 refuses to cover tests that could be "reasonable and

necessary" for some patients, of course a court could find the LCD arbitrary and capricious under the APA.[8] See 5 U.S.C. § 706(2)(A).

Additionally, Pacific Edge points out that Congress created a shortcut to challenge an LCD for *individuals*, not suppliers. See 42 U.S.C. 1395ff(f)(2). Because that provision outlines a clear process for challenging an LCD, Pacific Edge argues it is the *only* way to challenge an LCD. (4/16/25 Hr'g Tr. 7:11-19). If anything, this provision hurts Pacific Edge. Subsection (f) was added to the Medicare Act by the Medicare, Medicaid, and SCHIP Benefits Improvement and Protection Act of 2000. Pub. L. No. 106-554, § 1(a)(6), Title V, § 522(a). Significantly, prior versions of the bill considered by Congress would have given suppliers, like Pacific Edge, the ability to administratively challenge an LCD. See H.R. 4680, 106th Cong. § 221(a) (2000) (allowing "[p]ersons or classes of persons, who make, manufacture, offer, supply, make available, or provide [covered] items and services" to challenge an LCD). The purpose of this provision was to "ensure that all beneficiaries maintain a legitimate right to challenge in a timely manner, before an independent decisionmaker, any adverse coverage or claims decisions that may impact their ability to obtain quality health care." H.R. Rep. No. 106-703(I), at 71 (2000). When Congress made the clear choice to only allow individuals to challenge an LCD through the administrative process, it did not implicitly grant suppliers the ability to cut straight to federal court and seek relief under the APA. Rather, § 1395ff(f)(2) gives individuals a

[8] The Secretary has conceded that once Pacific Edge has gone through the administrative process for an individual claim appeal, it could then make its APA claim in federal court. (4/16/25 Hr'g Tr. 31:10-12, 21-24).

streamlined way to challenge an LCD, whereas institutional players must go through the individual claims process under § 1395ff(b)-(d).

Pacific Edge further objects that judicial review at that point would be deferential to the agency's decision; in other words, review would be deferential to the LCD. (See Doc. 38 at 15-16). But deference does not preordain defeat (or confer jurisdiction where none exists). See In Touch Home Health Agency, Inc. v. Azar, 414 F. Supp. 3d 1177, 1194 (N.D. Ill. 2019) ("Moreover, despite federal courts' deferential review [of] agency decisions, obtaining relief in federal court remains possible."). Second, Pacific Edge's basis for asserting a "district court does not review whether the LCD is valid," (Doc. 38 at 16), is a single, unreported decision from the Southern District of Texas—Clinic Resources Management v. Burwell, No. CIV.A. H-14-578, 2015 WL 3932657 (S.D. Tex. June 26, 2015). Among the issues with relying solely on Clinic Resources, is that the plaintiff in that case was not challenging the LCD wholesale but the application of the LCD. See Clinic Resources, 2015 WL 3932657 *5-6. Nowhere was there a claim in that case that the LCD violated the APA. As such, the court is not persuaded Clinic Resources stands for the proposition that an LCD's validity cannot be challenged under the APA once properly in federal court.

Finally, in a last-ditch effort to avoid the Illinois Council analysis, Pacific Edge asserts Weinberger v. Salfi, 422 U.S. 749 (1975) provides an alternative path to jurisdiction in this case. (See Doc. 38 at 22). Salfi held that § 405 allows the Secretary to "specify such requirements for exhaustion as he deems serve his own interests in effective and efficient administration." Salfi, 422 U.S. at 766. Thus, the

Secretary can waive whether a challenger must first proceed through the administrative process before going to court. In Salfi, the Secretary "d[id] not raise any challenge to the sufficiency of the allegations of exhaustion in appellees' complaint." Id. at 767. This is plainly not the case here, (See Doc. 30 at 18-22), and so Salfi is inapplicable.

The court is cognizant of the dire consequences the non-coverage of Cxbladder tests will have on Pacific Edge. The company has also marshalled incredibly compelling facts for why its test is a medical marvel. Yet the law is clear: a party may only avoid Medicare's challenging requirement when it would otherwise have "no review at all." Illinois Council, 529 U.S. at 19. Pacific Edge will have access to review through the individual claims reconsideration process once L39365 take effect. While this undoubtably will cause Pacific Edge (and perhaps individuals) "delay related hardship," it is the price to be paid for stability in the Medicare system, and it is a price Congress has decided is worth paying. See id. at 13. This court's hands remain tied.

IV. Conclusion

The Illinois Council exception to Medicare's channeling requirement does not apply in this case. As such, this court does not have jurisdiction over Pacific Edge's present claim. Accordingly, Defendants' motion to dismiss will be granted and Pacific Edge's motion for a preliminary injunction or summary judgment will be denied as moot. An appropriate order shall issue.

/S/ KELI M. NEARY
Keli M. Neary
United States District Judge
Middle District of Pennsylvania

Dated: April 23rd, 2025